Guidance For Industry

INSTRUCTIONS FOR COMPLETION OF MEDICAL DEVICE REGISTRATION AND LISTING FORMS FDA 2891, 2891a AND 2892

Prepared by
Division of Small Manufacturers Assistance
Office of Health and Industry Programs

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July 1997

Comments on these instructions should be submitted for agency consideration by writing to Bryan H. Benesch, CDRH, 1350 Piccard Drive, HFZ-220, Rockville, MD 20850 or by E-mail to bhb@cdrh.fda.gov. For questions regarding the use of this guidance, also contact the Division of Small Manufacturers Assistance at (301) 443-6597 or (800) 638-2041; or the Information Processing and Office Automation Branch, Office of Compliance at (301) 827-4555 (press 6, then press 2 for registration and listing)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland 20850

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Although this guidance does not create or confer any rights, for or on any person, and does not operate to bind FDA or the public, it does represent the agency's current thinking on the Registration and Listing regulations.

Where this document reiterates a requirement imposed by statute or regulation, the force and effect as law of the requirement is not changed in any way by virtue of its inclusion in this document.

ESTABLISHMENT REGISTRATION AND MEDICAL DEVICE LISTING

INTRODUCTION

Section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that domestic establishments engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and commercial distribution register their establishments with the Food and Drug Administration (FDA). This is accomplished by completing FDA Form 2891, "Initial Registration of Device Establishment." The term "device" is defined in section 201(h) of the FD&C Act and includes all in vitro diagnostic products and in vitro diagnostic biological products not subject to licensing under section 351 of the Public Health Service Act (42 U.S.C. 262). Foreign manufacturers commercially distributing devices in the United States (U.S.) are not required to register; however, they are encouraged to do so. Refurbishers/reconditioners are not required to register or list, however, FDA will accept voluntary registration and listings from firms that wish to be registered with FDA.

Section 510 of the Federal Food, Drug, and Cosmetic Act requires both domestic and foreign manufacturers to list their devices with FDA if the devices are in commercial distribution. Devices are listed by their classification name on form FDA 2892. A classification name is a generic category the device being listed would be placed in.

Neither registration nor listing constitutes FDA clearance or approval for marketing or commercial distribution in the U.S. Unless the device is exempt from the clearance or approval process, a premarket notification submission [510(k)] or a premarket approval application (PMA) is required before commercial distribution commences.

Registration of a device establishment or submission of device listing **does not** in any way denote approval of the establishment or its products by FDA. A firm may not advertise or distribute promotional material with any statement relating to its registration with FDA. Any labeling or other representation that creates an impression of official FDA approval is **misleading** and constitutes **misbranding** as referenced in section 301 of the FD&C Act and
21 CFR 807.39.

The regulations for registration and listing are in 21 CFR Part 807.

1. ESTABLISHMENT REGISTRATION

How To Register

To register an establishment, form FDA 2891, "Initial Registration of Device Establishment," must be completed. To order copies of the form see Appendix 2.

When registering, consider the following points:

- Submit all four (4) copies of the original registration form to the Center for Devices and Radiological Health (CDRH) to the address printed on the form.

- Do not use post office (P.O.) box numbers as addresses in Sections "A or B" of form FDA 2891. FDA will not accept P.O. box numbers. The actual street address must be used unless the only street address is a rural route box number or a highway mile number.

Where To Submit

All copies of form FDA 2891 are to be submitted to the following address:

Food and Drug Administration
Center for Devices and Radiological Health (HFZ-308)
2098 Gaither Road
Rockville, Maryland 20850
Telephone No. 301-827-4555 (Press 6, then press 2 for registration and listing)

Keep a photocopy of the registration form for your records.

INSTRUCTIONS FOR COMPLETION OF "INITIAL REGISTRATION OF DEVICE ESTABLISHMENT," FORM FDA 2891

All of the information provided on form FDA 2891 must be in English. When necessary, supplemental sheets can be used to complete or clarify your submission. Supplemental sheets must be letter size (8 ½ x 11 inches or A4) and have typed or printed in the upper right hand corner, the establishment business name from Block 2.

The numbers below refer to the item numbers on form FDA 2891.

1. **Registration No.** Leave this space blank. The Food and Drug Administration (FDA) will assign a unique registration number to each establishment.

   SECTION A. The purpose of this section is to obtain specific information about the registering establishment.

2. **Establishment Business Name.** Enter the legal name of the establishment involved in registration activity and limit the entry to 50 characters (abbreviate only if necessary).

3. **Record Date.** Enter the month, day, and year the form is completed using a MM/DD/YYYY date format. All entries must be numeric and two/four digits each as shown below for July 4, 1997:

	Mo	Day	Year
	07	04	1997

4. **Number and Street.** Enter the number and street at which the registering establishment is located. Do not use Postal Box or Rural Route numbers. Limit entry to 60 characters for the street address.

   Domestic Establishments:

5. **City and Foreign State.** Enter the city name in which the establishment is located. Limit entry to 30 characters.

6. **State.** Enter the two-character State code of the U.S. Postal Service for the State, territory, or possession.

7. **ZIP Code +4.** Enter the U.S. Postal ZIP Code +4.

8. **Foreign Country.** Leave blank.

Foreign Establishments:

5. **City and Foreign State.** Enter the city and foreign state (i.e., province, prefecture, region, territory) names in which the establishment is located. Limit entry to 30 characters, abbreviate if necessary (e.g., Vancouver, B.C.

6. **State.** Leave blank.

7. **Zip Code/Postal Code.** Enter the foreign country Postal Code/Zip Code. Limit entry to 10 characters.

8. **Foreign Country.** Enter the foreign country name.

Both Domestic and Foreign Establishments:

9. **Establishment Type.** Space is provided for each designated code for establishment type. Select from the following list of establishment types the appropriate codes that reflect the device activities of the establishment. Definitions for each establishment type appear in Appendix 3. Circle all of the letter designation(s) that apply to the establishment (e.g., M and C, or S and ID, etc.)

C CERTIFYING SITE/MDR REPORTING SITE.
DD** DOMESTIC DISTRIBUTOR.
E* CONTRACT MANUFACTURER.
M MANUFACTURER.
R REPACKAGER AND/OR RELABELER
S SPECIFICATION DEVELOPER.
T* CONTRACT STERILIZER.
U U.S. DESIGNATED AGENT.
X REMANUFACTURER.
ID INITIAL DISTRIBUTOR.
K*** REFURBISHER/RECONDITIONER

* *NOTE: A September 1, 1993 Federal Register notice erroneously exempted contract manufacturers and contract sterilizers from registration. That exemption will be revoked*

****NOTE: Since 1995, FDA has exercised its enforcement discretion and is not currently requiring or accepting registration or listing forms from domestic distributors.**

***NOTE: Refurbishers/reconditioners are not required to register and list, however, CDRH will accept voluntary registrations and listings. To do so, print or type the letter "K" in one of the empty boxes in Block number 9.

10. **Pre-production Registration**. To be used only when registering prior to commencing actual production, otherwise check NO. A pre-production registration will be held by CDRH for only one (1) year. After one year CDRH automatically notifies the firm that it must register as an active firm. If the establishment does not notify CDRH that it has begun an activity that requires registration, the pre-production registration form will then be archived without further processing. The establishment must notify CDRH by letter when their status has changed to "in production or active" and submit a Device Listing form, FDA 2892, if one is required. At that time the initial registration form will be further processed and a registration number issued.

SECTION B. The purpose of this section is to obtain information about the owner or operator of the registering establishment.

Both Domestic and Foreign Establishments

11. **Owner/Operator Business Name.** Enter the business trading name of the corporation, subsidiary, affiliated company, or partnership that is the owner or operator of the registering establishment. **Only enter the proprietor's name if no other business trading name exists.** Limit entry to 50 characters (abbreviate only if necessary).

12. **Owner/Operator I.D.** Fill in if an Owner or Operator I.D. number has been previously issued by CDRH. Leave this space blank if no identification number has been issued by CDRH. CDRH will assign an identification number and provide this to the registrant.

13. **Number and Street.** Enter the number and street at which the owner or operator is located. Limit entry to 60 characters for the street address.

Domestic Establishments

14. **City and Foreign State.** Enter the city in which the owner or operator is located. Limit entry to 30 characters.

15. **State.** Enter the two-character State code of the U.S. Postal Service for the State, territory, or possession.

16. **ZIP Code +4.** Enter the U.S. Postal ZIP Code +4.

17. **Foreign Country.** Leave blank.

18. **Telephone Number.** Enter the area code and/or country plus city codes and telephone number, including extension, **only** if the number is different from that of the official correspondent. If there is a toll free (800 or 888) number, CDRH requests it be given.

Foreign Establishments

14. **City and Foreign State.** Enter the city and foreign state names (i.e., province, prefecture, region, territory) in which the owner or operator is located. Limit entry to 30 characters.

15. **State.** Leave blank.

16. **Zip Code/Postal Code.** Enter the foreign country Postal Code. Limit entry to 10 characters.

17. **Foreign Country.** Enter the foreign country name.

18. **Telephone Number.** Enter the country code, city code and telephone number, including extension, **only** if the number is different from that of the official correspondent.

SECTION C. The purpose of this section is to identify the individual designated as official correspondent. FDA will direct important correspondence to the individual identified in this section.

19. **Official Correspondent/U.S. Designated Agent.** Enter the name of the individual designated as the official correspondent for registration and listing purposes. The name must be neatly printed or typed.

The requirement in 21 CFR 807.40 to have a U.S. Designated Agent has been placed in abeyance, as of July 23, 1996, so do not provide this information. There is no existing requirement to employ a U.S. Designated Agent, so foreign establishments do not need to hire one. The Official Correspondent requirement is not in abeyance and must be completed.

20. **Registration Number.** Leave blank since this was intended for the registration number of the U.S. Designated Agent.

21. **Business Name**. Enter the name of the establishment, owner or operator, or other place of business, as applicable, with which the official correspondent is associated. This may be the same name as, or different from, Block 2 or Block 11. Limit entry to 50 characters.

22. **Number and Street.** Enter the number and street or post office box of the official correspondent's place of business. A Post Office box number is acceptable in Section C, since this address will be used for FDA mailings. Limit entry to 60 characters for the street address.

Domestic Establishments:

23. **City.** Enter the city name in which the official correspondent's place of business is located. Limit entry to 30 characters.
24. **State.** Enter the two-character State code of the U.S. Postal Service for the State, territory, or possession.

25. **ZIP Code +4.** Enter the U.S. Postal ZIP Code +4.

Foreign Establishments:

23. **City, Foreign State and Country.** Enter the city, state and country name in which the official correspondent's place of business is located. Limit entry to 30 characters. The form does not have a separate item for State and Country because the U.S. Designated Agent provision required all official correspondent's to be located in the United States. While this provision is in abeyance, please provide the Foreign State and Country information in this block or on a supplemental page.

24. **State.** Leave blank.

25. **Postal Code/ZIP Code.** Enter the foreign country Postal Code. Limit entry to 10 characters.

Both Domestic and Foreign Establishments:

26. **Telephone Number.** Enter the area code and/or country plus city codes and telephone number, including extension, of the official correspondent, as it would be dialed from the U.S. If there is a toll free (800 or 888) number, CDRH requests it be given.

27. **FAX Number.** Enter the area code and/or country plus city codes and the FAX machine number of the official correspondent, as it would be dialed from the U.S.

SECTION D. The purpose of this section is to record other names for the registering establishment that relate to device activities and that are different from the name entered in Section A.

28. **Other Business Trading Name.** Enter any other establishment names used, using one of the six blocks for each name. **This can include "d.b.a." (doing business as) names.** Limit entry in each block to 50 characters. Use an attached sheet if the number of names exceeds six. **Do not include the names of distributors for whom this establishment makes devices. Do not list registered trademarks in use by the firm.**

SECTION E. The signature (29) and title (30) of the designated official correspondent must appear in this section.

Exhibit 1: FDA Form 2891

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

INITIAL REGISTRATION OF DEVICE ESTABLISHMENT

(Shaded Areas are for FDA Use Only)

Form Approved: OMB No. 0910-0059.
Expiration Date: February 28, 1999

VALIDATION

RETURN THIS FORM TO: Food and Drug Administration, Center for Devices and Radiological Health, (HFZ-308), 2098 Gaither Road, Rockville, MD 20850

1. **REGISTRATION NO.**

Public reporting burden for this collection of information is estimated to average .25 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DHHS, Reports Clearance Officer
Paperwork Reduction Project (0910-0316)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Please **DO NOT RETURN** this form to this address,

NOTE: This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C. 331(p)). Persons who violate this provision may, if convicted, be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), U.S.C. 331(q)(2) and may be a violation of 18 U.S.C. 1001.

SECTION A

2. ESTABLISHMENT BUSINESS NAME		3. RECORD DATE *(Mo.) (Day) (Yr.)*	
4. NUMBER AND STREET	5. CITY AND FOREIGN STATE	6. STATE	7. ZIP CODE
8. FOREIGN COUNTRY	9. ESTABLISHMENT TYPE *(See Instructions Booklet)* C DD E M R S T U X ID	10. PREPRODUCTION REGISTRATION YES NO	

SECTION B

11. OWNER/OPERATOR BUSINESS NAME		12. OWNER/OPERATOR I.D.	
13. NUMBER AND STREET	14. CITY AND FOREIGN STATE	15. STATE	16. ZIP CODE
17. FOREIGN COUNTRY	18. TELEPHONE NUMBER-IF DIFFERENT FROM THAT OF OFFICIAL CORRESPONDENT *(Area Code) (Number & Extension)*		

SECTION C

19. OFFICIAL CORRESPONDENT/U.S. DESIGNATED AGENT		20. REGISTRATION NUMBER	
21. BUSINESS NAME			
22. NUMBER AND STREET	23. CITY	24. STATE	25. ZIP CODE
26. TELEPHONE NUMBER *(Area Code) (Number and Extension)*		27. FAX NUMBER *(Area Code) (Number)*	

SECTION D

28. **OTHER BUSINESS TRADING NAMES**
(Enter any other name which the establishment in field #2 uses. Do not list Registered trademarks or names of private label distributors. This is usually any name such as a brand name which is not the firm name).

SEQ	BUSINESS NAME	SEQ	BUSINESS NAME
SO1		SO4	
SO2		SO5	
SO3		SO6	

SECTION E

29. SIGNATURE OF OFFICIAL CORRESPONDENT	30. TITLE

FORM FDA 2891 (5/96) **PREVIOUS EDITIONS ARE OBSOLETE.** *** U.S. GPO: 1996-404-897/41025**

INSTRUCTIONS FOR COMPLETION OF "ANNUAL REGISTRATION OF DEVICE ESTABLISHMENT," FORM FDA 2891a

Introduction

Each year active, registered establishments will receive a pre-printed annual registration form FDA 2891a from CDRH. This form is to be used to notify FDA of changes to the current registration information for the establishment. **Only those items needing changes or corrections need be completed.** This form must be returned to CDRH even if no changes have occurred. The form comes with three parts and is pre-addressed for return to CDRH. After detaching Parts 1 and 3 and retaining for your company files, fold Part 2 in half and it becomes a mailer requiring only the addition of first class or air mail postage.

All of the information provided on form FDA 2891a must be in English. When necessary, supplemental sheets can be used to complete or clarify your submission. Supplemental sheets must be letter size (8 ½ x 11 inches or A4) and have typed or printed in the upper right hand corner, the registration number of the firm.

The letters below refer to the block letters on form FDA 2891a.

A. Type of Submission. Complete block A by checking one box according to the following instructions:

No change. Check this box if all of the information printed to the left of Blocks B, C, D, E, or F is correct and complete. Check the "NO CHANGE" box on the outside of the mailer.

Correction. Check this box if any information printed to the left of Blocks B, C, D, E, or F is incorrect or incomplete. Make corrections, additions, or deletions in the corresponding blocks. Check the "CHANGE" box on the outside of the mailer.

No Longer Device Establishment. Check this box if the establishment is no longer engaged in activities (see establishment types in Appendix 3) which require it to be registered as a medical device establishment, but the establishment is still in existence for other activities or purposes. If any of the information printed to the left of Blocks B, D, or F is incorrect, this information should be corrected. Check the "CHANGE" box on the outside of the mailer.

Out of Business. Check this box if the establishment has ceased to exist as an identifiable organization. Make changes to information printed to the left of Blocks B, C, D, E, or F so that the information reflects the current information at the time the establishment went out of business. Check the "CHANGE" box on the outside of the mailer.

B. Registered Establishment Information. Indicate any changes or corrections to the information in block B. If the establishment type has changed to M, R or S, then a new or initial Device Listing form FDA 2892 must be submitted for all the medical devices marketed by the firm that are affected by this change. Previously listed devices may also need to have updated forms FDA 2892 submitted.

C. Establishment Type. Indicate any changes or corrections to the information in block C. (See Establishment Types in Appendix 3).

D. Owner/Operator Information. Indicate any changes or corrections to the information in block D.

E. Other Business Trading Names. Indicate any changes or corrections to the information in block E.

F. Official Correspondent/U.S. Designated Agent Information. Indicate any changes or corrections to the information in block F. The U.S. Designated Agent provision is in abeyance, as of July 23, 1996, so do not provide this information.

G. Official Correspondent Signature and Title Line. The official correspondent must sign, date, and print or type title.

Mailing Instructions

After Part 2 of the form is completed, it should be folded in half with the CDRH address on the outside. Tape (DO NOT STAPLE) where indicated. Check the "CHANGE" or "NO CHANGE" box as appropriate on front of the mailer. Affix first-class or air mail postage and mail. **Retain Part 1 for your records, do not return Part 1 to CDRH.**

Exhibit 2: FDA Form 2891a - Front Page

REGISTRATION NO.: FOR: OWNER/OPERATOR NO.:	DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION **ANNUAL REGISTRATION OF DEVICE ESTABLISHMENT**	NOTE: This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C. 331(p)). Persons who violate this provision may, if convicted be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(Q)(2), (21 U.S.C. 331(Q)(2)) and may be a violation of 18 U.S.C. 1001

REGISTERED ESTABLISHMENT	OWNER/OPERATOR

OFFICIAL CORRESPONDENT	ESTABLISHMENT TYPE
	Detach Part 1 and Keep as Proof of Registration. Complete and Return Part 2. Detach and Refer to Part 3 for Specific Instructions.

Form FDA 2891(a) (5/98) Part 1 - Keep for Your Records Form Approved: OMB No. 0910-0059 Expiration Date: February 28, 1999

(BAR CODE)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

ANNUAL REGISTRATION OF DEVICE ESTABLISHMENT

A| TYPE OF SUBMISSION (Mark one ☒ only)
- ∔ No Change
- ∔ Correction
- ∔ No Longer Device Establishment
- ∔ Out of Business

REGISTERED ESTABLISHMENT INFORMATION

B| CORRECTIONS TO REGISTERED ESTABLISHMENT INFORMATION
Establishment Name
Number and Street
City State
Zip Country

ESTABLISHMENT TYPES (If information below is inaccurate, correct in column to right)

∔ C Certifying Site/MDR Piping Site ∔ OD Distributor ∔ E Contract Manufacturer ∔ M Manufacturer
∔ R Repackager and/or Relabeler ∔ S Specification Dev ∔ T Contract Sterilizer ∔ U U.S. Designated Agent
∔ ID Inhet Distributor ∔ X Remanufacture

C| CORRECTIONS TO ESTABLISHMENT TYPE (To correct, mark ☒ all which correctly apply)

∔ C Certifying Site/MDR Piping Site ∔ OD Distributor ∔ E Contract Manufacturer ∔ M Manufacturer
∔ R Repackager and/or Relabeler ∔ S Specification Dev ∔ T Contract Sterilizer ∔ U U.S. Designated Agent
∔ ID Inhet Distributor ∔ X Remanufacture

OWNER/OPERATOR INFORMATION

D| CORRECTIONS TO OWNER/OPERATOR INFORMATION
Business Name
Number and Street
Number and Street
City State
Zip Country
Phone No. ( ) Ext.
Owner/Operator Number

OTHER BUSINESS TRADING NAMES

E| CORRECTIONS TO TRADING NAMES (If name on left has errors, write corrected name on line to its right. If no longer used, write "DELETE". Write new names last, preceded by and asterisk.

OFFICIAL CORRESPONDENT INFORMATION

F| CORRECTIONS TO OFFICIAL CORRESPONDENT / U.S. DESIGNATED AGENT
Name of Individuals
Business Name
Number and Street
Number and Street
City State Zip
Registration Number
Phone No. ( ) Ext. FAX No. ( )

G| SIGNATURE OF OFFICIAL CORRESPONDENT / U.S. DESIGNATED AGENT

TITLE OF OFFICIAL CORRESPONDENT / U.S. DESIGNATED AGENT

DATE SIGNED

Form FDA 2891 Part 2 - Complete and Return Form Approved: OMB No. 0910-0059 Expiration Date: February 28, 1999

(BAR CODE)

INSTRUCTIONS FOR COMPLETING FORM FDA 2891a
ANNUAL REGISTRATION OF DEVICE ESTABLISHMENT

1. DETACH PART 1. *KEEP THIS PART FOR YOUR RECORDS AS PROOF OF REGISTRATION.*
2. Review Part2 for changes and corrections. Complete Block A by checking one box according to the instructions below.
   Make corrections in Blocks B, C, D, E, and F as indicated. See reverse side of Part 3 for definitions.
   No Change- Check this box if all of the information printed to the left of Blocks B, C, D, E, and F is correct and complete. Check the "NO CHANGE" box on the outside of the mailer.
   Correction- Check this box if any information printed to the left of Blocks B, C, D, E, or F is incorrect or incomplete. Make corrections, additions, or deletions in the corresponding blocks. Check the "CHANGE" box on the outside of the mailer.
   No Longer Device Establishment- Check this box if the establishment is no longer engaged in activities (see establishment types) which require it to be registered as a medical device establishment, but the establishment is still in existence for other activities or purposes. If any of the information printed to the left of Blocks B, D, or F is incorrect, this information should be corrected. Check the "CHANGE" box on the outside of the mailer.
   Out of Business- Check this box if the establishment has ceased to exist as an identifiable organization. Make changes to information printed to the left of Blocks B, C, D, E, or F so that the information reflects the current information at the time the establishment went out of business. Check the "CHANGE" box on the outside of the mailer.
3. Sign and Mail Part 2
   Sign- *Official Correspondent must sign, date, and provide title in Block G. Photocopy Part 2 for your records, if desired.*
   Mail- Fold form in half with FDA address to outside. Tape (do NOT staple) where indicated. Check "CHANGE" or "NO CHANGE" box as appropriate on front of mailer. Affix first class postage and mail.

Part 3 - Instructions

Exhibit 2: FDA Form 2891a - Back Page

Food and Drug Administration
Center for Devices and Radiological Health
Information Processing and
Office Automation Branch (HFZ-308)
2098 Gaither Road
Rockville, MD 20850-4015

☐ **CHANGE**
☐ **NO CHANGE**

ESTABLISHMENT TYPE DEFINITIONS

ESTABLISHMENT TYPE - Space is provided for each designated code for establishment type. Select from the following descriptions the appropriate code or codes that reflect the device activity of the of the establishment. Enter the letter designation(s) in the space provided.

C **CERTIFYING SITE/MDR REPORTING SITE**-Registered site responsible for submission of the annual certification of the number of MDR reports submitted.

DD **DISTRIBUTOR** - Is any person who furthers the marketing of a device from the original place of manufacture, to the person who makes final delivery or sale to the ultimate consumer or user, but does not repackage, or otherwise change the container, wrapper, or labeling of the device or device package. This also includes, but is not limited to, direct sale, mail order, leasing, distributing promotional samples, distributing demonstration units, and drop shipping. Distributor does not include brokers or other persons who do not own the device, but merely perform a service for the person (other than the ultimate consumer) who does own the device. *NOTE: The requirement for registration of a domestic distributor is currently not being enforced pending revocation of this requirement.*

E ***CONTRACT MANUFACTURER**- Manufactures a finished device to another establishment's specifications. The manufacturing establishment does not commercially distribute the device under its own name.

M **MANUFACTURER**-Makes by chemical, physical, biological, or other procedures, any article that meets the definition of device of "device" in section 201(h) of the Federal Food, Drug, and Cosmetic (FD&C) Act.

R **REPACKAGER AND/OR RELABELER**- *Repackager*: Packages finished devices from bulk or repackages devices made for the establishment by a manufacturer into different containers (excluding shipping containers). *Relabelers*: Changes the content of the labeling from that supplied from the original manufacturer for distribution under the establishment's own name. (This does not include establishments that do not change the original labeling but merely add their own name.)

S **SPECIFICATION DEVELOPER**-Develops specifications for a device that is distributed under the establishment's own name but performs no manufacturing.

T **CONTRACT STERILIZER**-Provides a sterilization service for another establishment's devices.

U **U.S. DESIGNATED AGENT**-Person designated by owner or operator of a foreign establishment responsible for the annual certification of the number of MDR reports.

ID **INITIAL DISTRIBUTOR**-Takes first title to imported devices.

X **REMANUFACTURE**-Persons who rebuild used device to new operating specifications for the purpose of redistribution.

**NOTE: A September 1, 1993 Federal Register notice erroneously exempted contract manufacturers and contract sterilizers from registration. That exemption will be revoked.*

FORM FDA 2891a (5/96)

Before sealing, did you remember to ...

1. Check a box in Block A?
2. Sign and Date Block G?
3. Check "Change" or "No Change" on the front mailer?
4. Affix first class postage?

Public reporting burden for this collection of information is estimated to average .25 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DHHS, Reports Clearance Officer
Paperwork Reduction Project (0910-0059)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

Please **DO NOT RETURN** this form to this address.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

RETAIN FOR YOUR RECORD

FORM FDA 2891a (5/96)

2. MEDICAL DEVICE LISTING

How To List

Listing a device is done by completing form FDA 2892, Device Listing. To aid in completing this form, CDRH provides an on-line, searchable product classification database on its World Wide Web Home Page, **http://www.fda.gov/cdrh/prodcode.html.** See Appendix 4 for instructions on how to use the database for obtaining the proper classification name(s) and number(s) to complete Blocks 7 and 8 of Form FDA 2892. This information can also be found in the CDRH publication titled, "Classification Names for Medical Devices and In Vitro Diagnostic Products." Copies can be obtained from the Division of Small Manufacturers Assistance (DSMA) or the Information Processing and Office Automation Branch (IPOAB) (See Appendix 2 for ordering information).

When listing, remember these points:

- **Submit only original listing forms**. Form FDA 2892 **must not** be reproduced because of the preprinted document number. The preprinted document number in Block 1 represents the company and the product listed on the form. CDRH will **not** accept photocopies of form FDA 2892. CDRH will now accept computer-generated facsimiles of the form FDA 2892 which use the document number from a preprinted form. The blank preprinted form must then be attached to the computer-generated facsimile so that its unique number is not used again. The original copy of the computer-generated form must be submitted. To receive approval to use computer-generated facsimiles of the FDA 2892, submit a copy of the proposed facsimile to the IPOAB (see Appendix 2 for address).

- When completing Blocks 7 and 8 of the device listing form, pay particular attention to the classification name and number as they represent the generic category of devices an establishment intends to market. The classification number is also referred to as the FDA product code or FDA code. You will find both product codes and classification names in the on-line database mentioned above, or FDA publication titled, "Classification Names for Medical Devices and In Vitro Diagnostic Products." **If you cannot find a classification name or number, then contact DSMA or IPOAB. Additional classification names and numbers are periodically added or updated by CDRH and may not be in the publication but will be in the on-line database. In addition, the classification number can be found in your marketing clearance letter for 510(k) and PMA applications cleared starting in 1994. You may also attach a description of the device to the FDA 2892 and request assistance in determining the classification name and/or number. To assist CDRH, this description should include a copy of the device labeling, possible classification names or numbers, and 510(k) or PMA numbers.**

Listing For Foreign Establishments

Foreign establishments that export medical devices to the United States **are required** to list the devices with FDA on form FDA 2892, "Device Listing."

Things to remember are that:

- Foreign establishments may list their products directly with FDA by completing and submitting the device listing form FDA 2892.

- Foreign establishments for which there exists joint ownership and control with a domestic U.S. establishment may have the domestic establishment submit the device listing form FDA 2892. A letter explaining this relationship must be submitted to FDA by the foreign establishment with the appropriate forms, FDA 2891 (Initial Registration form) or FDA 2892.

- Foreign establishments for which there is no joint ownership and control with a domestic U.S. establishment may comply with the listing requirement by authorizing a **sole** initial U.S. distributor to complete the listing form FDA 2892 on their behalf. A **sole initial distributor** is an "exclusive distributor of a specific device imported from a foreign manufacturer," that is, they are the **only** distributor in the U.S. importing specific devices from a specific manufacturer.

  To authorize a sole initial distributor to list on behalf of a foreign manufacturer and maintain a historical listing file, the foreign manufacturer must provide the distributor with a "**letter of authorization**." This letter should state that: " [named distributor] is the sole initial domestic U.S. distributor of a [specific device] and they are authorized to list on behalf of [the manufacturer] and maintain their historical listing file." The "letter of authorization" must accompany the Device Listing form FDA 2892, be on the foreign establishment’s letterhead and be in English, for the device listings to be valid. In addition, the "letter of authorization" should only pertain to the specific device for which the importer will be the sole source.

INSTRUCTIONS FOR COMPLETION OF MEDICAL DEVICE LISTING FORM FDA 2892

Introduction

All of the information provided on form FDA 2892 must be in English. When necessary, supplemental sheets can be used to complete or clarify your submission. Supplemental sheets must be letter size (8 ½ x 11 inches or A4) and have typed or printed in the upper right hand corner, the preprinted document number from Block 1 for that submission.

Any item(s) submitted for listing purposes (i.e., letter of authorization, labeling may be needed to determine classification name and number, catalog pages, etc.) must have the document number from Block 1 of Form 2892 for that submission entered on each separate item. This material is only necessary if a firm cannot determine the appropriate classification name or number to use.

Completion Of Form FDA 2892

The FDA controls all listing submissions based upon the preprinted document number in Block 1 of form FDA 2892. Form FDA 2892 is a three-part form. The yellow copy is a file copy for the owner or operator and must be detached before sending the two white copies to CDRH.

The two white copies of the form FDA 2892 are to be submitted to the following address:

Food and Drug Administration
Center for Devices and Radiological Health
Information Processing and Office Automation Branch (HFZ-308)
2098 Gaither Road
Rockville, Maryland 20850 USA

Any correspondence with CDRH relating to a specific listing must reference its document number from Block 1. The document number is not to be interpreted as a license or approval number and it shall not be used on your device labeling.

The numbers below correspond to block numbers on form FDA 2892:

1. **Document Number.** Preprinted number which is to be referenced in any correspondence with FDA regarding a specific device.

2. **Reason for Submission.** Check the appropriate reason.

3. **Report Date.** Enter the actual date that the form FDA 2892 was completed by you. The date format is 07/04/1997 or MM/DD/YYYY.

4. **Owner/Operator ID Number.** Enter in Block 4 the seven-digit number assigned to the owner or operator when the establishment registered with FDA. The owner or operator ID is located in Block 12 of form FDA 2891, and is also on form FDA 2891a. If the firm has not previously registered or listed, and therefore no owner or operator number has been received at the time of making an initial listing, then leave this block blank. The owner/operator ID number will be entered by CDRH when assigned.

   Foreign establishments that are not registered will leave Block 4 blank. CDRH will assign an owner or operator ID number and send the firm a letter specifying what the number is. After CDRH has assigned this number, it should be used on all FDA 2892 forms subsequently submitted.

5. **Owner/Operator Name.**

   Domestic: Enter in Block 5 the business trading name of the corporation, subsidiary, affiliated company, or partnership that is responsible for completing and submitting the device listing information.

   Foreign: Enter in Block 5 the foreign owner or operator's business trading name of the corporation, subsidiary, affiliated company, or partnership that is responsible for completing and submitting the device listing information.

   Domestic or Foreign: Only enter the proprietor's name if no other business trading name exists. When applicable, this name should be the same name as was entered in Block 11 on form FDA 2891, "Initial Registration of Device Establishment" or in Section D of form FDA 2891a, "Annual Registration of Medical Device Establishment."

6. **Address.** Enter the full street, city, state/foreign state, zip code +4 or postal code and foreign country. If this address is the same as submitted on form FDA 2891, please check the box provided, but still complete this block in its entirety.

7. **Classification Name.** Enter the classification name for the generic category of the device. The classification name can be found in the on-line product classification database (see Appendix 4), or in the CDRH publication entitled "Classification Names for Medical Devices and In Vitro Diagnostic Products." **DO NOT ENTER "NONE" OR "MULTIPLE" IN THIS BLOCK.** If you cannot determine the classification name, consult your marketing clearance letter, or provide the 510(k) number or PMA number or regulation number of the product. Otherwise contact DSMA for assistance.

8. **Classification Number (FDA Code or FDA Product Code).** Enter the three letter alpha character code (ignore the two numbers) from the classification list that corresponds to the classification name you have selected, or enter the code that appears on the marketing clearance letter. Again, the classification list appears in the on-line database, or in the CDRH publication entitled "Classification Names for Medical Devices and In Vitro Diagnostic Products." If you can not determine the classification number provide the 510(k), PMA or regulation number of the device. Otherwise, contact DSMA for assistance. Do not confuse this number with the seven digit regulation number assigned to each type of device classified in the Code of Federal Regulations, Parts 862-892.

9. **Proprietary Name (Brand Name).** Enter the proprietary name, such as the trade, brand or catalog name of the device. Use only those abbreviations in the proprietary name that appear on the label or labeling. Exclude as part of the device proprietary name any reference to physical characteristics such as size, package shape, or color. If more than one proprietary name is used for the device or devices being listed, enter "Multiple" in Block 9. Limit entry to 80 characters.

10. **Common or Usual Name.** FDA recognizes that no "established names" for devices have been designated pursuant to section 508 of the Act and that few "official titles" for devices are recognized in an official compendium. Consequently, the common or usual name must be provided in order to satisfy the listing requirement. The common or usual name can be any descriptive phrase and does not have to have industry-wide or user acceptance. Limit entry to 80 characters.

    If the common or usual name is the same as that entered for the proprietary name, enter "SAME" in Block 10.

    If more than one device is being listed under one classification name, enter a descriptive phrase which represents the group of devices, i.e., "Various Types of Rongeurs," or "Various Models of X-Ray Systems."

    If one or more devices represented by a classification name is labeled and marketed as "sterile," include the word sterile as part of the common or usual name, i.e., "Various Types of Sterile and Non-sterile Syringes."

    If the device is an "accessory" or a "kit," then include these words as part of the common or usual name, i.e., "Accessory to an Endoscope," "Wound Dressing Kit," "First Aid Kit."

11. **Designated Agent.** This requirement is **not** in effect so leave it blank.

    The requirement in 21 CFR 807.40 to have a U.S. Designated Agent has been placed in abeyance, as of July 23, 1996, so do not provide this information. There is no existing requirement to employ a U.S. Designated Agent, so foreign establishments do not need to hire one.

12. **Establishment Name and Address.**

    Provide registration number, name and address, and establishment type information as follows:

    Registration No.: If you have already registered, enter in Block 12, line A the registration number of the manufacturing site from your copy of form FDA 2891 or FDA 2891a. If the establishment is not registered, then leave blank. The only firms to be listed in Block 12 are those registered by the owner or operator listed in Block 5 or foreign establishments that elect not to register.

    Foreign owner or operators that do not have a registration number should enter "NONE" under registration number in Block 12. Foreign owner or operators should not identify their sole initial distributors unless the distributors are owned by the foreign firm and they are required to be listed.

    Name and Address. Enter in Block 12 the name of the establishment where the listed device is produced. "Establishments" include those performing specifications development and repackaging or relabeling activities. For registered establishments the name should be identical to the name on your copy of form FDA 2891 or FDA 2891a. The only names to be entered in block 12 are those associated with, owned or substantially controlled by, the owner or operator listed in Block 5 and are the actual locations or where listed devices are manufactured. No contract manufacturer names should be listed unless owned or substantially controlled by owner or operator listed in Block 5.

Establishment Type.

Foreign Establishments: If your company is a manufacturer then place a mark (X) below "M" on Line A.

Domestic Establishments: Place a mark (X) in Block 12 under the appropriate letter code or codes from the list of establishment types that appear in Appendix 3 that describe the activities that occur at the establishment. You may check as many codes as apply.

Examples:

a. If an establishment site is involved only in the development of specifications, enter a mark (X) in the "S" column for that establishment.

b. If an establishment site manufactures and labels a device with its company name(s) only, enter a mark (X) in the "M" column for that establishment.

13. **Signature.** The Official Correspondent, or sole initial distributor completing form FDA 2892 must sign in the space provided.

14. **Name.** Type or print neatly the name of the individual who signed Block 13.

Exhibit 3: FDA Form 2892

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DEVICE LISTING

Form Approved: OMB No. 0910-0059.
Expiration Date: February 28, 1999

Complete and Return to: Food and Drug Administration
Center for Devices and Radiological Health
Information Processing and Office Automation Branch (HFZ-308)
2098 Gaither Road
Rockville, MD 20850

NOTE: This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C. 331(p)). Persons who violate this provision may, if convicted be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(g)(2), (21 U.S.C. 331(g)(2) and may be a violation of 18 U.S.C. 1001.

1. DOCUMENT NUMBER	2. REASON FOR SUBMISSION	3. REPORT DATE	4. OWNER/OPERATOR ID NUMBER
	☐ New Listing ☐ Update to Device Already Listed ☐ Delete Listing	MO. | DAY | YR.	

5. OWNER/OPERATOR NAME

6. ADDRESS ***(Check*** ☐ *if same as submitted on FDA Form 2891)*

a. NUMBER and STREET

b. CITY, STATE, ZIP CODE	c. FOREIGN COUNTRY

7. CLASSIFICATION NAME	8. CLASSIFICATION NUMBE R

9. PROPRIETARY NAME ***(Brand Name)***

10. COMMON OR USUAL NAME

11. FOR U.S. DESIGNATED AGENTS OF FOREIGN ESTABLISHMENTS

a. NAME	B. REGISTRATION NUMBER

12.

ESTABLISHMENT NAME AND ADDRESS
(Identification of Sites Where Listed Device is Produced)

REGISTRATION NO. (Name, Street Number, City, State or County, ZIP or Postal Code)	ESTABLISHMENT TYPE							
	M	R	S	T	X			
A								
B								
C								
D								

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DHHS, Reports Clearance Officer
Paperwork Reduction Project (0910-0059)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Please **DO NOT RETURN** this form to this address,

13. SIGNATURE	14. TYPED OR PRINTED NAME

FORM FDA 2892 (5/96) **PREVIOUS EDITIONS ARE OBSOLETE.** *** U.S. GPO: 1996-416-979/40511**

APPENDIX 1

ERRATA INFORMATION REGARDING 21 CFR 807

Due to changes in the location of the Center for Devices and Radiological Health and new registration and listing forms, certain information in the 1996 edition of the Title 21 Code of Federal Regulations is incorrect. The following is a partial list of corrected information by section number.

§807.25(f)(2), (f)(3), (f)(5), (f)(6)(i), (f)(6)(iii) are not currently being asked for on the Form FDA 2892.

§807.30 The Block numbers cited in this section are all incorrect. Here are the correct citations:

§807.30(a): Block 2 is no longer used to indicate the preprinted original document number of the 2892 used to initially list the device. This information now appears in Block 1.

§807.30(b)(5)(i): The owner or operator name is now Block 5. The owner or operator number is now Block 4.

§807.30(b)(5)(ii): The information previously in Blocks 12, 12a, 13, 13a and 14 is no longer requested. The information previously in Blocks 15, 16 and 17 is now in Block 12.

§807.30(b)(6): The information previously in Blocks 10 and 11 is in Blocks 9 and 10.

APPENDIX 2

HOW TO ORDER REGISTRATION AND DEVICE LISTING FORMS AND CLASSIFICATION NAMES BOOK

Forms FDA 2891 and 2892 may be ordered in quantity (>100 copies) from:

Consolidated Forms and Publication Center
Washington Commerce Center
3222 Hubbard Road
Landover, MD 20785 USA

Forms FDA 2891 and 2892 and their instructions may be ordered in any quantity from:

1) Publications, HFZ-220
Division of Small Manufacturers Assistance
Office of Health and Industry Programs
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850 USA
Phone No. 800-638-2041 x 102, 301-443-6597 x102, or Fax No. 301-443-8818

and

2) Information Processing and Office Automation Branch, HFZ-307
Office of Compliance
Center for Devices and Radiological Health
2098 Gaither Road
Rockville, MD 20850 USA
Phone No. 301-827-4555 (Press 6, then press 2 for registration and listing)

HFZ-308 is used just for identifying mail containing registration and listing forms and updates.

CLASSIFICATION NAMES for MEDICAL DEVICES and IN-VITRO DIAGNOSTICS PRODUCTS

This publication can also be ordered from the Division of Small Manufacturers Assistance at the address listed above item 1.

APPENDIX 3

ESTABLISHMENT TYPE DEFINITIONS

C CERTIFYING SITE/MDR REPORTING SITE. Registered site responsible for submission of the annual certification of the number of MDR reports submitted.

DD DOMESTIC DISTRIBUTOR. Any person who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user, but does not repackage, or otherwise change the container, wrapper, or labeling of the device or device package. This category also includes, but is not limited to, direct sale, mail order, leasing, distributing promotional samples, distributing demonstration units, and drop shipping. Distributor does not include brokers or other persons who do not own the device, but merely perform a service for the person (other than the ultimate consumer) who does own the device. *NOTE: Since 1995, the requirement for registration of a domestic distributor has not been enforced pending revocation of this requirement.*

*E CONTRACT MANUFACTURER. Manufactures a finished device to another establishment's specifications. The manufacturing establishment does not commercially distribute the device under its own name.

M MANUFACTURER. Makes by chemical, physical, biological, or other procedures, any article that meets the definition of "device" in section 201(h) of the Federal Food, Drug, and Cosmetic (FD&C) Act.

R REPACKAGER AND/OR RELABELER

Repackager: Packages finished devices from bulk or repackages devices made for the establishment by a manufacturer into different containers (excluding shipping containers).

Relabeler: Changes the content of the labeling from that supplied from the original manufacturer for distribution under the establishment's own name. A relabeler does not include establishments that do not change the original labeling but merely add their own name.

S SPECIFICATION DEVELOPER. Develops specifications for a device that is distributed under the establishment's own name but performs no manufacturing.

*T CONTRACT STERILIZER. Provides a sterilization service for another establishment's devices.

U U.S. DESIGNATED AGENT. Person designated by the owner or operator of a foreign establishment responsible for the annual certification of the number of MDR reports. **[This requirement has been in abeyance since July 23, 1996.]**

X REMANUFACTURER. Any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.

ID INITIAL DISTRIBUTOR. Takes first title to devices imported into the United States.

K*** REFURBISHERS: persons who, for the purpose of resale or redistribution, visually inspect, functionally test and service devices, as may be required, to demonstrate that the device is in good repair and performing all the functions for which it is designed. The device may or may not be cosmetically enhanced. Preventive maintenance procedures are performed. Refurbishers do not significantly change a finished device's performance or safety specifications, or intended use.

K*** RECONDITIONERS: persons who, for the purpose of resale or redistribution, visually inspect, functionally test and service devices, as may be required, to demonstrate that the device is in good repair and performing all the functions for which it is designed. The device may or may not be cosmetically enhanced. Preventive maintenance is not performed. Reconditioners do not significantly change a finished device's performance or safety specifications, or intended use.

* *NOTE: A September 1, 1993 Federal Register notice erroneously exempted contract manufacturers and contract sterilizers from registration. That exemption will be revoked.*

***NOTE: Refurbishers/reconditioners are not required to register or list, however, FDA will accept voluntary registration and listings from firms that which to be registered with FDA.

APPENDIX 4

HOW TO OBTAIN CLASSIFICATION NAME, CLASSIFICATION NUMBER OR PRODUCT CODE (PROCODE) INFORMATION FROM THE CDRH HOME PAGE

The Center for Devices and Radiological Health (CDRH) maintains a home page on the World Wide Web. This page contains a wealth of information about medical devices. To assist establishments with the device listing and premarket notification processes, CDRH is providing an on-line searchable database of product classification names and numbers, device classification information and their 510(k) exemption status.

The database can be accessed by going to the CDRH Home Page (http://www.fda.gov/cdrh) using any Internet browser software. The database is located at:

http://www.fda.gov/cdrh/procode.html

This takes you to an introduction page entitled Product Code Classification Database. At the bottom of the page, click on "Go directly to the Product Code Database search." This takes you to the "Search" page. You can either enter and search on the name of the device, or go to the medical specialty or panel that you think the product is in. The medical specialty option will find all the classification names for that panel of products.

Once you find the classification name and product code, enter this information in Blocks 7 and 8, respectively, on form FDA 2892.